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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,253	02/09/2006	Nagarajan Kuppuswamy	033899-0113	5990

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EXAMINER

CHO, JENNIFER Y

ART UNIT	PAPER NUMBER
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1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/535,253	Applicant(s) KUPPUSWAMY ET AL.	
	Examiner Jennifer Y. Cho	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 10-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/18/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Acknowledgment is made of the Information Disclosure Statement filed 5/18/2005.

Claim Objections

Claim 7 is objected to because of the following informalities: The language "preferably 5.15 C deg" is not clear. Appropriate correction is required. The Examiner suggests that the Applicant should correct the spelling to "preferably 5-15 deg C".

Claims 10-12 are objected to because of the following informalities: Claim 10 refers to "Gabalactam of the formula 3" which is not explained or depicted within the claim language. The claims should be self-explanatory from a reading of the claims. Appropriate correction is required. The Examiner suggests that the chemical structure of Gabalactam should be included in claim 10.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peverali et al. (US 6,518,456), in view of Cannata et al. (US Patent Publication 2004/0068011).

Peverali et al. teaches a process for the preparation of gabapentin by preparing an aqueous solution of gabapentin hydrochloride in water in the ratio of one part by weight of gabapentin hydrochloride to 2.3 part by weight of water (column 5, lines 30-32, example 6). An 30% sodium hydroxide aqueous solution is then added to the gabapentin solution at a temperature of 23°C to adjust the pH to 7.1 to 7.2 (column 5, lines 33-36, example 6). The solution is heated to 50°C to 55°C then to 60°C to 65°C (column 5, lines 38-41, example 6). The solution is then cooled to 10°C to 15°C and then aged to keep the precipitate solution at this temperature for a period of one hour (column 5, lines 42-43, example 6). The precipitate is separated by centrifugation (column 5, lines 44, example 6) and recrystallized with water and ethanol to give gabapentin in 99.7 % purity, with additional mother liquor (column 5, lines 44-67, example 6).

Peverali et al. is deficient in the sense that it does not teach recrystallization of the precipitate from a mixture of isopropyl alcohol, methanol and water.

Cannata et al. teaches the purification and recrystallization of gabapentin with isopropyl alcohol, methanol and water (page 2, section 28).

As far as the temperature levels and the percentage of alkali metal base, Peverali et al. teaches a temperature of 23°C and an alkali metal base solution of 30% for alkali addition to the gabapentin solution (column 5, lines 33-36, example 6). Though Peverali et al. does not teach Applicant's exact temperature and percentage, it is the position of the examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the optimization of these limitations to provide the best effective variable depending on the results desired. Thus it would be obvious in the optimization process to optimize the temperature and alkali metal percentage. The applicant does not show any unusual and/or unexpected results for the limitations stated. Note that the prior art provides the same effect desired by applicant, the preparation of gabapentin with over 99.5% purity.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to select suitable temperatures and percentages, since it is well-known that a variety temperatures and alkali metal percentages can be used to neutralize a gabapentin hydrochloride solution. Absent any showing of unusual and/or unexpected results over applicant's particular limitations for the addition of a sodium hydroxide solution to gabapentin hydrochloride, the art obtains the same effect on the

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purity of gabapentin. The expected result would be an improved process for the preparation of gabapentin with high purity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho *JC*
Patent Examiner
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